

1. Product Identification.

Lactose Ph Eur: Tabletose 70, Tabletose 80, Sorbolac 400, Pulmolac 400, Prismalac 40, Capsulac 60, Spheroiac 100, Granulac 140, Granulac 70, Granulac 200, Granulac 230, Sachelac 80, Flowlac 100.

2. Composition/ Information on Ingredients.

Lactose EP PhEur. is the monohydrate of 4-0-(β -D-Galactopyranosyl)- α -D-glucopyranose (Lactose Monohydrate DAB, EP, USP)

3. Hazards Identification.

No hazardous product in the meaning of the above mentioned regulations. Lactose is a natural product and a component of foodstuffs.

4. First Aid Measures.

Eyes: After contact, thoroughly rinse with water.
Skin: After contact, thoroughly rinse with water.

5. Fire Fighting Measures.

Extinguishing Media: Water
Fire & Explosion Hazards: Take precautions to avoid dust explosion and electrostatic charge.

6. Accidental Release Measures.

Recovery: Spilled product must be wiped up mechanically.

7. Handling & Storage.

Storage: Not to be stored together with explosive or incendiary material. Not to be stored close to strongly smelling substances.
Handling: According to our present data available not hazardous in the meaning of the corresponding EEC regulations and according to work medium regulation of 11.2.82 but the usual precautionary measures as applied for the handling of chemical should be adhered to.

8. Exposure Controls and Personal Protection.

Occupational Exposure Limits
Engineering Measures: Technical protective measures – no special methods necessary.

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Personal Protective Equipment

Respiratory: Do not breathe in dust
Eye: Avoid contact with eyes. Keep available eye rinse flask.

9. Physical and Chemical Properties.

Appearance: White Powder
Odour: Odourless
pH (as delivered): 4.0 – 6.5 (at 100g/l water, 20⁰C)
Melting Point: 201 – 203.5⁰C
Flash Point: None
Bulk Density: 330 – 390 g/l (Sorbolac 400, Pulmolac 400)
450 – 550 g/l (Prismalac 40, Granulac 200, 230)
500 – 600 g/l (Tabletose 70, 80)
540 – 660 g/l (Capsulac 60)
550 – 650 g/l (Granulac 140, Flowlac 100)
650 – 750 g/l (Granulac 70, Sachelac 80)
370 – 770 g/l (Sphrolac 100)
Relative Density (SG): 1.525 g/cm³
Solubility: In water 16.1% (20⁰C)

10. Stability & Reactivity.

Hazardous Decomposition Products: Not before change in state.

11. Toxicological Information.

Short Term: According to work medium regulation of 11.2.1982 the product is neither toxic nor detrimental to health. It is not mentioned in annexes 1 and 11. Detrimental effects on health are not possible owing to harmlessness of product.

12. Ecological Information.

Aquatic Toxicity: The product is neither contained in the list of agents dangerous to water nor in the list according to TA-regulations referring to air.

13. Disposal Considerations.

The elimination has to be done in accordance to the actual regulations of municipal authorities waste. 9see also item 3, page 1)

14. Transport Information.

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Non-hazardous product in the meaning of the transport regulations.

15. Regulatory Information.

Applicable Regulations: According to the present data available the product is non-hazardous in the meaning of the corresponding EEC regulations and according to work medium regulation of 11.2.1982. But the usual precautionary measures as applied for the handling of chemicals should be adhered to.

16. Other Information.

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